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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,698	02/10/2000	ODILE LEROY	99849-A	7060

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/423,698	LEROY, ODILE	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 6-15-06 has been entered.

It is noted that no new arguments have been submitted and no discussion over the newly presented documents have been presented.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Information Disclosure Statement

The information disclosure statement submitted on 6-15-06 has been considered. It is noted that references 2 and 3 did not include either a presentation date at the symposia or a publication date and therefore the examiner could not ascertain if the citations were prior art against the instantly claimed invention. An initialed copy is enclosed.

Rejections Maintained

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al (Infection and Immunity, 40(1):245-256, April 1983) in view of Merck and Co. Inc. (EP 0497 525, May 8, 1992).

The claims are drawn to compositions per se comprising conjugates of polysaccharides from *S. pneumoniae* serotype/serogroup coupled to a carrier protein as defined by the formula in claim 1 and further limited in dependent claims.

Chu et al teach a composition comprising two or more conjugates comprising a bacterial polysaccharide coupled to a carrier protein. In particular, when two or more conjugates were injected they were admixed in a single syringe (see page 247, column 2, "Immunization"). Chu et al teach the combination of *Haemophilus influenzae* Type b (Hib) and Pneumococcal Type 6A polysaccharide (Pn6A) protein conjugates. Hib was conjugated to horseshoe crab hemocyanin (HCH) and Pn6A was conjugated to tetanus toxin (TT) and were administered together (Table 3, page 250; different carbohydrates and different carriers). Additionally, the polysaccharide K100 from *E. coli* was conjugated to TT or to HCH and was administered in combination with either Hib-HCH or Hib-TT respectively (see page 249, Table 2). The Hib and K100 conjugates were administered at 1.25 ug of polysaccharide and when in combination with Pn6A, each was injected at 2.5 ug polysaccharide. At these levels, the levels of TT or HCH administered is below 50 ug/dose (see Table 1, column 1, page 249). Chu et al also teach that when Hib-HCH was injected with either Pn6A-HCH or Pn6A-TT, both the anti-Hib and anti-Pn6A responses were increased over that induced by either conjugate alone (see abstract, page 245). Chu et al also teach that the injection of two conjugates did not exert a negative effect (page 253, column 1, first full paragraph). Chu et al teach that the conjugates were capable of inducing protective levels of both polysaccharides and carrier proteins (see abstract). Chu et al teach that the experiments have shown that a "useful" carrier is as effective as a "nonsense" carrier in mice. Therefore, it would seem that a "useful" carrier would be preferred in human use (page 254, column 1, first full paragraph). Chu et al differs by not teaching both carbohydrates from *S. pneumoniae* serotype/serogroup being the same or different.

Merck and Co. Inc. teach conjugates of partially hydrolyzed, highly purified, capsular polysaccharide (Ps) from *Streptococcus pneumoniae* serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11 a, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F and 33F conjugated to a protein moiety (PRO) wherein the PRO that should behave as an immune enhancer and

that such immune enhancers are the outermembrane protein complex (OMPC) derived from *Neisseria miningitidis*, tetanus toxin, diphtheria toxin or pertussinogen may be used (page 3, lines 14-19 and page 16, lines 54-59). Merck and Co. Inc, teach vaccines comprising a mixture from one to ten different pneumococcal polysaccharide-immunogenic protein conjugates (Pn-Ps-PRO) induce broadly protective recipient immune responses against cognate pathogens (see abstract; paragraph bridging pages 2-3 and page 50, claim 10). Merck and Co. Inc. indicate that a polyvalent vaccine comprising 23 unconjugated *Streptococcus pneumoniae* (Pn) polysaccharides is commercially available as "PNEUMOVAX^{TM}23" and accounts for 90 percent of pneumococcal blood isolates. Merck and Co. Inc, teach that the unconjugated vaccines are least effective in the elderly and infants under two years of age, and this is the segment of the population most at risk for pneumococcal infections. Merck and Co. Inc. teach that since unconjugated polysaccharides are poor inducers of T-cell immune responses, conversion of the Pn-Ps into immunogens capable of inducing T-cell responses is the key to producing adequate protection in this target population. (see page 2, second full paragraph).

As to claims 1-12 and 14 it would have been *prima facie* obvious to one of ordinary skill in the art to modify the conjugate composition of Chu et al by combining any of the additional Pn-Ps-PRO conjugates of Merck and Co Inc. to provide for a conjugate composition containing up to 10 different Pn-Ps-PRO conjugates because Merck and Co Inc. teach that vaccines comprising a mixture from one to ten different pneumococcal polysaccharide-immunogenic protein conjugates (Pn-Ps-PRO) induce broadly protective recipient immune responses against cognate pathogens and Merck and Co Inc teach that the PRO portion of the conjugate may be an immune enhancer such as diphtheria or tetanus toxoid (TT or DT). As to claims 16, 17, 18 and 21, it would have been *prima facie* obvious to one having ordinary skill in the art at the time that the invention was made to substitute the protein DT of Merck and Co Inc for the HCH in the Hib-HCH conjugate of Chu et al because Chu et al teach that a "useful" carrier would be preferred in human use

(page 254, column 1, first full paragraph) and Merck and Co. Inc. teach that PRO that should behave as an immune enhancer and that such immune enhancers are the outermembrane protein complex (OMPC) derived from *Neisseria miningitidis*, tetanus toxin, diphtheria toxin or pertussinogen may be used in conjugate vaccines for human use. As to claims 1-24, it would have been further *prima facie* obvious to one of ordinary skill in the art to modify the conjugate composition of Chu et al by adding any of the additional Pn-Ps-PRO conjugates of Merck and Co Inc. to provide for a conjugate composition containing up to 23 different Pn-Ps-PRO conjugates because Merck and Co Inc. teach that vaccines comprising a mixtures of different pneumococcal polysaccharide-immunogenic protein conjugates (Pn-Ps-PRO) induce broadly protective recipient immune responses against cognate pathogens, Merck and Co Inc teach that the PRO portion of the conjugate may be an immune enhancer such as TT or DT and the combination of all 23 polysaccharide serotypes would provide the benefit of covering 90 percent of pneumococcal blood isolates (disease causing).

Status of Claims

All claims stand rejected.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

AU 1645